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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/416,828	10/12/1999	WILLIAM STEVE AMMONS	27129/33638A	6675

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EXAMINER
ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 02/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/416,828	Applicant(s) AMMONS ET AL.	
	Examiner David S Romeo	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed 12/07/2001 (Paper No. 7) has been entered. Claims 1-5, 8-10 are pending and being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

The terminal disclaimer filed on 12/07/2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5578568 and 6017881 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The declaration under 37 CFR 1.132 filed 12/07/01 is sufficient to overcome the rejection of claims 1-3, 6-10 based upon 35 U.S.C. 103(a) as being unpatentable over Gathiram (C6, cited by Applicants) in view of Theofan (a6), and, if necessary, further in view of Boermeester (C4, cited by Applicants) and the rejection of claims 1, 4, 5 based upon 35 U.S.C. 103(a) as being unpatentable over Gathiram (C6, cited by Applicants) in view of Theofan (a6) and, if necessary, further in view of Boermeester (C4, cited by Applicants), as applied to claim 1 above, and further in view of Caty (YY, cited by Applicants).

Maintained Formal Matters, Objections, and/or Rejections:

Claims 1-5, 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing the duration of bradycardia by administering BPI, does not reasonably provide enablement for a method of reducing the duration of cardiac arrhythmia by administering a BPI protein product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants argue that they have fully supported the recitation of "BPI protein product" and that they teach a wide variety of biologically active analogs and variants of BPI which are the subject of co-owned patents and applications which incorporated by reference. Applicants arguments have been fully considered but they are not persuasive. The present claims are of essentially limitless breadth because, as used herein, "BPI protein product" includes biologically active polypeptide analogs or variants of either bactericidal/permeability-increasing protein or biologically active fragments thereof (page 4, lines 23-29). Biologically active analogs and variants of BPI include, BPI protein products wherein one or more amino acid residues have been replaced by a different amino acid (page 6, lines 10-12). There are no limits on the number and type of amino acids that may be replaced. The claims encompass essentially any and all compounds that achieve the desired results, including those unrelated to BPI, because all of the amino acids in BPI could be replaced. The specification lacks guidance for making, and working examples of, compounds unrelated to BPI that achieve the desired results.. The scope of claims

does not bear a reasonable correlation to scope of enablement provided by the present specification, even in view of analogs and variants of BPI which are the subject of co-owned patents and applications which incorporated by reference, because the claims encompass compounds unrelated to BPI.

Applicants point out that the parent and grandparents of the present application recite "BPI protein product" in their claims. This has been noted by the examiner. Suffice it to say that each case must be decided on its own merits based on the evidence of record.

Page 9, lines 20-25, and Figure 6 have been considered but they are not persuasive. Stedman's Medical Dictionary (u9) refers to cardiac dysrhythmia for a definition of cardiac arrhythmia and defines cardiac dysrhythmia as any abnormality in the rate, regularity, or sequence of cardiac activation. "Cardiac arrhythmia" as recited in the present claims is generic to and encompasses tachycardia. As noted in the last Office action at page 4, lines 9-11, the administration of a BPI protein product appears to induce tachycardia. The specification lacks guidance for reducing the duration of tachycardia with an agent that induces tachycardia.

Claims 1-5, 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that they have fully supported the recitation of "BPI protein product" and that they teach a wide variety of biologically active analogs and variants of BPI which are the subject of co-owned patents and applications which incorporated by reference. Applicants

arguments have been fully considered but they are not persuasive. The present claims are of essentially limitless breadth because, as used herein, "BPI protein product" includes biologically active polypeptide analogs or variants of either bactericidal/permeability-increasing protein or biologically active fragments thereof (page 4, lines 23-29). Biologically active analogs and variants of BPI include, BPI protein products wherein one or more amino acid residues have been replaced by a different amino acid (page 6, lines 10-12). There are no limits on the number and type of amino acids that may be replaced. The claims encompass essentially any and all compounds that achieve the desired results, including those unrelated to BPI, because all of the amino acids in BPI could be replaced. The claims are directed to or encompass a genus of "BPI protein products" The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to BPI. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, BPI and $rBPI_{21}$ cys alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in

possession of the claimed genus. Note that using the term "BPI protein" instead of "BPI protein product" may overcome the rejection with respect to the description of the term "BPI protein product".

Applicants point out that the parent and grandparents of the present application recite "BPI protein product" in their claims. This has been noted by the examiner. Suffice it to say that each case must be decided on its own merits based on the evidence of record.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 10 are indefinite because they recite the term "BPI protein product". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "BPI protein product" an artisan cannot determine what additional limitations are placed upon a claim by the presence of this term. Note that using the term "BPI protein" instead of "BPI protein product" may overcome the rejection with respect to the indefiniteness of the term "BPI protein product".

Applicants argue that they have fully supported the recitation of "BPI protein product" and that they teach a wide variety of biologically active analogs and variants of BPI which are the subject of co-owned patents and applications which incorporated by reference. Applicants arguments have been fully considered but they are not persuasive. As used herein, "BPI protein product" includes biologically active polypeptide analogs or variants of either bactericidal/permeability-increasing protein or biologically active fragments thereof (page 4,

lines 23-29). Biologically active analogs and variants of BPI include, BPI protein products wherein one or more amino acid residues have been replaced by a different amino acid (page 6, lines 10-12). There are no limits on the number and type of amino acids that may be replaced. The claims encompass essentially any and all compounds that achieve the desired results, including those unrelated to BPI, because all of the amino acids in BPI could be replaced. The metes and bounds are not clearly set forth.

Applicants point out that the parent and grandparents of the present application recite "BPI protein product" in their claims. This has been noted by the examiner. Suffice it to say that each case must be decided on its own merits based on the evidence of record.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
FEBRUARY 20, 2002